REMARKS

Summary of Prosecution

A Notice of Allowance and Fees Due was mailed from the U.S. Patent and Trademark Office on December 15, 2004. The issue fee was paid on January 31, 2005. A Notice of Withdrawal From Issue Under 37 C.F.R. §1.313(b) was mailed from the U.S. Patent and Trademark Office on May 6, 2005. The Notice of Withdrawal From Issue stated that the above-referenced application was withdrawn from issue after payment of the issue fee for an interference.

Pursuant to the contact information on the Notice of Withdrawal From Issue, on May 23, 2005 Mary K. Murray, Applicants' Attorney, spoke to Examiner Nelson of the U.S. Patent and Trademark Office. Examiner Nelson confirmed that a request for an interference had been filed with the Patent Office and directed Mary K. Murray to contact Examiner Lankford regarding the status of the case. On June 8, 2005, Mary K. Murray spoke with Examiner Lankford, who stated that he was reviewing the Request for Declaration of Interference. Thereafter, Applicants received an Office Action mailed from the U.S. Patent and Trademark Office on July 13, 2005. On July 19, 2005, Mary K. Murray spoke with Examiner Lankford regarding the Office Action.

In view of completion of prosecution, the Notice of Allowance, payment of the Issue Fee, the Notice of Withdraw From Issue and conversations with Examiners Nelson and Lankford, the recent mailing of an Office Action, not prompted by any amendment or submission of prior art by Applicants, is a cause of concern to Applicants regarding the pace of prosecution. As noted in Section 707.07(g) of the Manual of Patent Examining Procedure (8th edition, August 2001, Revised May 2004) (hereinafter "MPEP") "piecemeal examination should be avoided as much as possible."

Rejection of Claims 14, 19-21, 23 and 25 under 35 U.S.C. §112, First Paragraph

Claims 14, 19-21, 23 and 25 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that the claims contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention or in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." The Examiner further stated that Applicants generically claim any isolated cell population from bone marrow which co-express CD49c and CD90; however, the specification does not contain an adequate description for the entire scope of the limitations of the generic claim. In addition, the Examiner stated that the claims are essentially of limitless breadth and that a generic statement without more, is not an adequate written description of the genus because it does not distinguish the claimed species of the genus from the others. Further, the Examiner stated one skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity the members of the genus claimed by Applicants.

Applicants note that Claim 26 was also previously allowed and pending. Applicants' response to the Examiner's rejections include Claim 26.

As a preliminary matter, Applicants fail to understand the nature of the rejection made. Specifically, the Examiner begins by stating that Claims 14, 19-21, 23 and 25 are rejected under 35 U.S.C. §112, first paragraph, as failing to meet the written description requirement, but then explains that the specification fails to "enable one skilled in the art to make and/or use the invention." The Examiner does not provide reasoning that would support a rejection under either the written description requirement or the enablement requirement of the first paragraph of 35 U.S.C. §112. For example, in the first paragraph, after setting forth the statutory basis for rejection, the Examiner states that Applicants claim any isolated cell population from bone marrow which co-expresses CD49c and CD90 and then summarily concludes that the specification does not contain an adequate description for the entire scope of this limitation and thus the claims, presumably on the basis, presented in the next sentence, that the claims are not limited to a particular species, but "just generically any cell population with those 2 cell surface antigens." There is no allegation, or support for an allegation, by the Examiner of a lack of predictability associated with this invention among species. Further, the Examiner does not explain what other limitations Applicants are lacking. Instead, only the implication that some undefined set of limitations must be provided to meet the written description requirement.

Similarly, the Examiner states that the doubling rate of the claimed isolated cell population does not serve "as much of a further limitation" because, "according to the Applicant,

the doubling rate is a result of culture conditions." Page 24, lines 18 through 23 of Applicants' Amendment filed December 22, 2003, Applicants states:

> Applicants' claimed cell population, as amended, is believed to be a consequence of cultured cells derived from bone marrow under low oxygen conditions, such as 5% oxygen, as described in the specification on, for example, page 2, lines 25-29; page 4, lines 7-9; page 8, lines 10-12; page 11, line 24 through page 12, line 1; page 14, lines 20-23; page 15, lines 6-8; and page 20, lines 4-6.

Applicants belief as to the mechanism associated with forming the claimed isolated cell population is immaterial and, contrary to the Examiner's suggestion, does not affect whether the phrase "wherein the cell population has a doubling rate of less than 30 hours" constitutes a claim limitation. On the contrary, regardless of the culture conditions, Applicants' claimed isolated cell population is distinguished, at least in part, by the fact that the cell population exhibits a doubling rate of less than about 30 hours.

In the following sentence, the Examiner states that "the claims encompass at least cells that may or may not exist in other animals and also cells different than those actually disclosed which would have these 2 surface antigens but have not yet been reported." Applicants are unaware of any case law that precludes, under the written description requirement of 30 U.S.C. §112, claims from embracing undiscovered embodiments. As recited by the Examiner, from *In re Fisher*, 427 F.2d 833, 166 U.S.P.Q. 18 (CCPA 1970):

> [It is apparent that such an] inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. §112. That paragraph requires that the scope of claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment that provides broad enablement in the sense that, once imagined, other

> embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

As discussed above, there has been no allegation or support for an allegation of a lack of predictability in the factors identified by the Examiner, namely, "particular species," and "other animals and also other cells different than those actually disclosed which would have these two surface antigens but have not yet been reported."

In the following paragraph, the Examiner makes a statement with respect to the written description requirement:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus. See *Eli Lilly, 118 F.3d at 1568, 43 U.S.P.Q. 2d at 1406*

The Examiner, however, does not explain why Applicants' specification fails to meet the written description requirement. Rather:

- The Examiner asserts that the claims are "essentially of limitless breadth."
- The Examiner states that "it is implied that so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim, one can thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't."

The Examiner is mistaken; the claims are limited to an isolated cell population derived from bone marrow, wherein greater than about 91% of the cells of the cell population co-express CD49c and CD90, and wherein the cell population has a doubling rate of less than about 30

hours. Also, Applicants do not understand how a specification that provides one with the ability to test any particular embodiment which is encompassed by the material limitations of the claim supports an argument that the "claims are essentially of limitless breadth." Further, the Examiner does not identify what the "functional limitations" to which he is referring in the claims might be.

Without having explained how Applicants' claimed subject matter could be of "limitless breadth," and without identifying what "functional limitations" of the claims the Examiner considers to be inadequate to distinguish embodiments which are embraced and those which are not, the Examiner concludes that "the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of the working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record." As just discussed, the claims clearly are not of limitless breadth. The Examiner has not articulated any basis for lack of predictability among "particular species" or "in other animals and also cells different than those actually disclosed," as applied to this claimed invention, and, other than making broad allegations that Applicants are "implying" positions that the Examiner concludes are inconsistent with various decisions, such as, *In re Fisher*, *Amigen v. Chugai Pharmaceuticals* and *In re Wands*, the Examiner fails to support a rejection under the written description requirement of 35 U.S.C. §112.

In a subsequent paragraph, the Examiner simply states that "the claims imply that other cells with the claim designated properties can be found using the method disclosed in the specification without undue experimentation." Again, the Examiner does not identify what in the claims makes the implication referenced by the Examiner, nor does not Examiner identify the "method disclosed in the specification" to which he is referring. Without more, Applicants are unable to respond to this statement.

The Examiner then states:

> Whether or not the disclosure provides an enabling disclosure, it does not provide a written description of the desired cell population which is necessary to provide a written description of the claimed cell population.

In connection in with this statement, the Examiner references *Utter v. Hiraga*, 845 F.2d 993 (CAFC 1988) for the quotation, "A specification may, within the meaning of § 112, first

paragraph, contain a written description of a broadly claimed invention without describing all species that claim encompasses." Applicants do not understand how this quotation from *Utter* supports the Examiner's preceding statement with respect to claimed invention.

The Examiner then makes three statements that are unsupported by the cited cases or are inapposite to Applicants' claimed invention and specification. In particular, the Examiner asserts that:

> In claims to a species from a genus, however, a generic statement without more, is not an adequate description of the genus because it does not distinguish the claimed species of the genus from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus because it is only an indication of what the genus does rather than what it is.

Fiers v. Revel, 984 F.2d 1164 (Fed.Cir. 1993), on which the Examiner relies for this statement, does not stand for the proposition made by the Examiner. In particular, the pages from *Fiers* identified by the Examiner, 1169 through 1171, address the position of the party Revel in a three-way interference. The interference count stated: "A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide." The court's opinion at page 1170, states:

> According to Revel, since the language of the count refers to a DNA and not to a specific sequence, the specification need not describe the sequence of the DNA in order to satisfy the written description requirement.

The Federal Circuit disagreed, but not on the basis that the claim was to a genus and that a genus claim "without more, is not an adequate description of the genus because it does not distinguish the claimed species of the genus from others." Nor did the court decline to grant Revel priority to the other parties, Fiers and Sugano, on the basis that one skilled in the art would not be able to, in contrast to a fully described genus, "visualize or recognize the identity of the members of the genus." The court also did not state that "a definition by function, does not

suffice to define a genus because it is only an indication of what the genus does, rather than what it is." Rather, the court denied Revel the priority date of his Israeli application because he did not provide any description of the claimed matter, other than by invoking language in the specification that was "similar to the interference count"; there was no identification of the nucleic acid sequence itself, nor a demonstration that the disclosed a method for isolating the DNA was enabling. The court, rather, held that:

> An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel specification does not do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coating for β-IF. A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA.

By way of contrast, with respect to the present application, Applicants reduced the claimed invention to practice by a method that is enabling.

Regarding *Fiers*, the party Sugano won the interference proceeding because, of the three parties, Sugano was the only party to have actually sequenced the DNA; only one DNA sequence was identified and Sugano was granted priority in a contest over a claim count that employed only generic language:

> We conclude that Sugano is entitled to rely on his disclosure as enabling since it sets forth a detailed teaching of a method for obtaining a DNA coding for β-IF and the Board did not err in determining that *Fiers* presented no convincing evidence impeaching the truth of the statements in Sugano's patent specification. We also conclude that Sugano's application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for β-IF and thus "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for β-IF]." . . . The Board correctly determined that Sugano's March 19, 1980 Japanese application satisfies the requirements of

> §112, first paragraph, and that Sugano thus met his burden to establish entitlement to that filing date.

Following reference to *Fiers*, the Examiner further states:

> It is only a definition of a useful result rather than a definition of what achieves that result. Many such species of the genus may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

For support, the Examiner relies on a statement in *In re Wilder*, 736 F.2d 1516, 1521 (Fed. Cir. 1984) and quoted a phrase stating that the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate." However, contrary to the Examiner's suggestion, the holding in *Wilder* was not on the basis that a generic claim in the application defined only a useful result rather than a definition of what achieves the result, nor on the basis that "the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention." Rather, Appellants in *Wilder* filed claims in a reissue application that were significantly broader than those of the original patent. The court held that broad statements in the drawing, the title and a section of the specification entitled, "Objects of the Invention," were inadequate to support a generic claim in an application where only one embodiment of the invention is disclosed in the original patent:

> Appellants admit that the synchronous scanning equipment is the only embodiment of the invention disclosed in the original patent. To overcome the board's decision, appellants point out that the description of one of the drawings says that dictation apparatus illustrated in the drawing is "one in which the present invention finds ready application." Appellants also note that the title of patent "Instruction Indicating Apparatus For A Record And/Or Playback Device" is quite broad." The general description of a drawing and broadly phrased title of the patent demonstrate, appellants content, that other embodiments are contemplated and are sufficient to satisfy the disclosure requirement. These phrases relied upon by appellants demonstrate a desire to claim the invention as broadly as the prior art would allow. But a desire to

> claim as broadly as possible is the objective of most applicants for a patent. The subjective desire does not establish that the broader invention being claimed in this reissue application is adequately described in the original patent. The broadly worded title of the original patent and customarily broad description of the drawing do not satisfy the description requirement in this case.

With respect to the "objects of the invention," the court stated:

> Appellants also rely on statements in the Objects of the Invention section of the specification to satisfy the description requirement . . . . They do not satisfy the disclosure requirement in this case. For instance, one of the recited objects says:
>
> > [I]t is an object of the present invention to provide improved indicating apparatus for indicating the location of a particular information on a record medium which overcomes the aforenoted problems.
>
> The "aforenoted problems" relate to difficulties associated with paper scales graduated in minutes previously used to note the approximate place on a tape where instructions were located. In our view, the board correctly read the Objects of the Invention as doing little more than outlining goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate. But the invention that achieves these general objectives must still be described. Appellants have not shown that the generic invention of Claims 14-16 as supported by the original patent's disclosure in such a way as would indicate possession, as of the original filing date, of that generic invention.

By way of contrast to the facts of *Wilder*, the language of the scope of Applicants' rejected claims is fully supported by the language of the specification as filed. The distinction between Applicants' specification and claims, and those of *Wilder*, is highlighted by a comparison made by the court in *Wilder* with another case, *In re Peters*, 723 F.2d 891 (Fed.Cir. 1983), wherein generic claim language was found to meet the requirements of 35 U.S.C. §112 despite the "exact and non-critical shape disclosed in the original patent":

> The present situation is to be distinguished from this court's recent decision in *In re Peters*, 723 F.2d 891 (Fed.Cir. 1983), brought to

> our attention by appellants. In *Peters*, the appellant successfully rebutted the PTO's rejection by proving that the broadened claims "merely omit an unnecessary limitation [the word "tapered"] that had restricted one element of the invention to the exact and non-critical shape disclosed in the original patent." *Id*, at 893. The court further commented: "Indeed, if the reissue claims had been submitted with the original application, it is difficult to perceive how they could have been properly rejected under §112." *Id* at 894.

Therefore, contrary to the Examiner's suggestion, the three cases recited, *Utter*, *Fiers* and *Wilder*, dictate that Applicants' invention, as claimed, in view of the specification filed, meets the written description requirement of 35 U.S.C. §112, first paragraph. Further, and also contrary to the Examiner's statement, Applicants have done more than "name a type of material generally thought to exist." Rather, Applicants have reduced the claimed invention to practice and have demonstrated possession of the invention claimed.

As stated in Section 2163, page 2100-170 of the May 2004 Revised Edition of the MPEP, possession of the claimed invention may be shown in many ways. Specifically:

> Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. (Emphasis added)

On page 2100-170, the MPEP also states:

> A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. (Emphasis added)

In addition, on page 2100-171, the MPEP states that possession of the claimed invention may be shown by the following:

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. (Emphasis added)

For claims drawn to a genus, on page 2100-174 the MPEP states:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the application was in possession of the claimed genus.

As stated on page 2100-175 of the MPEP, a "representative number" of species can be satisfied as follows:

> What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.

As stated in the Federal Register, Volume 66, Number 4, January 5, 2001 (hereinafter "Federal Register"), a single species can provide an adequate written description for generic claim. Specifically, on page 1102, the Federal Register states:

> The Guidelines now indicate that a single species may, in some instances, provide an adequate written description of a generic claim when the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus.

As noted on page 1106 of the Federal Register, factors to be considered in determining whether there is evidence sufficient possession can include the following:

> Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. (Emphasis added)

As discussed above, and contrary to the Examiner's statement, Applicants' invention, as claimed, is **not** essentially of "limitless breadth." Rather, Applicants' claimed invention, as set forth in Claim 14, 19-21, 23, 25 and 26, is directed to an isolated cell population derived from bone marrow, wherein greater than about 91% of the cells of the cell population co-express CD49c and CD90 and wherein the cell population has a doubling rate of less than about 30 hours. Further, Applicants have actually reduced to practice the claimed invention and constructed a cell population that meets the requirements of the claimed invention, as described on, for example, page 25, line 8 through page 37, line 9 of the specification.

In addition, the specification describes in sufficient detail, the relevant identifying characteristics of the claimed invention that provide evidence that Applicants were in possession of the claimed invention. Such identifying characteristics distinguish the claimed invention from other materials. For example, page 8, lines 1-2 describes a cell population that co-expresses CD49c and CD 90; page 10, lines 17-25 describes isolated cell populations derived from bone marrow that co-express CD49c and CD90; page 14, lines 4-6 describes isolated cell populations that co-express CD49c and CD90 with 30 population doublings; and page 21, lines 4-19 describe cell populations that co-express CD49c and CD90.

Therefore, contrary to the Examiner's assertion, the specification provides an adequate written description of the genus of the claimed invention. One of skill in the art would recognize that Applicants were in possession of the "necessary common attribute or features of the elements possessed by the members of the genus [e.g., derived from bone marrow; co-express CD49c and CD90; and a doubling rate of less than about 30 hours] in view of the species disclosed" in Applicants' specification, as set forth *supra* (MPEP, page 2100-175).

Applicants' description of the species of the claimed invention, "would evidence to one of ordinary skill in the art that the invention includes the genus," as set forth *supra* (Federal Register, page 1102). Further, the physical and chemical properties, functional characteristics and method of making the claimed invention are described in relevant, and sufficient detail, as noted above. The disclosure of the combination of these identifying characteristics distinguish the claimed invention from other materials and would lead one skilled in the art to the conclusion that the Applicants were in possession of the claimed species and, thus, an adequate written description of the generic claim has been satisfied. Therefore, the specification provides a written description that conveys with reasonable clarity to those skilled in the art that Applicants were in possession of the claimed invention, as set forth in Claims 14, 19-21, 23, 25 and 26.

SUMMARY AND CONCLUSIONS

The specification provides an adequate written description to support pending claims Claims 14, 19-21, 23, 25 and 26 by meeting the requirements for 35 U.S.C. §112, first paragraph. Therefore, Applicants respectfully request reconsideration and allowance of the claims under consideration. If the Examiner feels that a telephone conference would expedite prosecution of this application, he is invited to call Applicants' undersigned Attorney.

Respectfully submitted,

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